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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,479	05/10/2006	Steffen Goletz	GULDE-63	4918
91436 7590 05/19/2010 Fanelli Strain & Haag PLLC 1455 Pennsylvania Ave., N.W., suite 400 Washington, DC 20004				
EXAMINER				
GUSSOW, ANNE				
ART UNIT		PAPER NUMBER		
1643				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/540,479

Applicant(s)

GOLETZ ET AL.

Examiner

ANNE M. GUSSOW

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 79-83, 85-117 and 122-131 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 79, 80, 83, 85-87, 89, 92-95, 97-99, 101-107 and 111-116 is/are allowed.
- 6) ☒ Claim(s) 88, 96, 117, 130 and 131 is/are rejected.
- 7) ☒ Claim(s) 81, 82, 90, 91, 100, 108-110 and 122-129 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 98 and 110 have been amended.
Claims 1-78, 84, and 118-121 have been cancelled.
Claims 130 and 131 have been added.
2. Claims 79-83, 85-117, 122-131 are under examination.
3. The following office action contains NEW GROUNDS of Rejection.

Objections Withdrawn

4. The objection to claim 110 is withdrawn in view of applicant's amendment to the claim.

Rejections Maintained/ NEW GROUNDS of Rejection

Claim Objections

5. Claims 81, 82, 90, 91, 100, and 108-110 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

- a. Claim 90 fails to further limit claim 87 because the CDR sequence of SEQ ID No. 11 is not a CDR in SEQ ID No. 33 or 35. Claims 81, 82, 108-110 are included in this objection because they depend upon claim 90.
 - b. Claim 91 fails to further limit claim 87 because the sequences of SEQ ID Nos. 60, 62, 64, 66, and 68 do not include all of the CDRs of claim 87. These sequences only include SEQ ID Nos. 1, 3, and 5 (SEQ ID Nos. 60, 62, 64, and 66) or 7, 9 and 11 (SEQ ID No.68).
 - c. Claim 100 fails to further limit claim 95 because the sequence of SEQ ID Nos. 61, 63, 65, 67, and 69 do not include all of the CDRs of claim 95. These sequences only include SEQ ID Nos. 2, 4, and 6, (SEQ ID Nos. 61, 63, 65, and 67) or 8, 10, and 12 (SEQ ID No. 69).
6. Claim 117 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 87. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. The rejection of claims 88 and 96 and newly added claims 130 and 131 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

Applicant's arguments filed March 4, 2010 have been carefully considered by the examiner but they are deemed not to be persuasive. The response states that the specification provides guidance to one skilled in the art at the time the invention was made to make and identify equivalent canonical structural variants according to invention. For example, the specification defines "equivalent canonical structural variants": According to the invention, equivalent canonical structural variants are understood to be amino acid sequences differing from the initial sequences to such an extent that at least one amino acid is replaced in well-defined positions without changing the canonical class." (Specification at p. 13, first full paragraph.) ... the claims further provide that the claim-designated recognition molecule binds to a glycosylated MUC 1 tumor epitope. (see response pages 23-28)

In response to this argument, while applicant has defined "equivalent canonical structural variants" in the specification, the definition encompasses amino acid substitutions at any amino acid position. Thus, the instant claims read on variations at any amino acid position in the CDRs. While applicant is not required to describe each and every species of a claimed genus, one must describe a sufficient variety of species to reflect the variation within the genus. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus.

As set forth in the previous office action, mutation of a single amino acid residue may dramatically affect antigen binding (Rudikoff, 1982, as cited in the previous office action mailed November 4, 2009) and residues other than the CDR residues are essential for the structure of the antigen binding site (see DePascalis, 2002, Casset, 2003, and Vajdos, 2002, as cited in the previous office action mailed November 4, 2009).

Amendment of the claims to include the limitations of claims 112-129 in claims 88, 96, 130, and 131 may obviate this rejection.

Therefore after a fresh consideration of the claims and the evidence provided the rejection is maintained.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claim 117 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 117, as written, does not sufficiently distinguish over antibodies or recognition molecules as they exist naturally because claim 117 does not particularly point out any non-naturally occurring differences between the claimed recognition molecules and the structure of naturally occurring antibodies

In the absence of the hand of man, the naturally occurring antibodies are considered non-statutory subject matter (Diamond v. Chakrabarty, 206 U.S.P.Q. 193

(1980)). It should be noted that the mere purity of a naturally occurring product does not necessarily impart patentability (Ex parte Siddiqui, 156 U.S.P.Q. 426 (1966)). However, when purification results in a new utility, patentability is considered (Merck Co. v. Chase Chemical Co., 273 F.Supp 68 (1967), 155 USPQ 139, (District Court, New Jersey, 1967)). Amendment of the claims to recite "an isolated" or "purified" recognition molecules or similar language would obviate this rejection.

Conclusion

11. Claims 79, 80, 83, 85-87, 89, 92-95, 97-99, 101-107, and 111-116 appear to be in condition for allowance.

Claims 88, 96, 117, 130, and 131 are rejected

Claims 81, 82, 90, 91, 100, and 108-110 are objected to.

Claims 122-129 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow
May 18, 2010

/Anne M. Gussow/
Examiner, Art Unit 1643